

08-16-06

IFW



Please type a plus sign (+) inside this box ☐

☐ +

PTO/SB/21 (6-99)

Approved for use through 09/30/2000. OMB 0651-00.  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>		Application Number	10/575,291
		Filing Date	April 11, 2004
		First Named Inventor	Kingston Mills
		Group/Art Unit	Unassigned
		Examiner Name	Unassigned
Total Number of Pages in This Submission		Attorney Docket Number	43369-0001

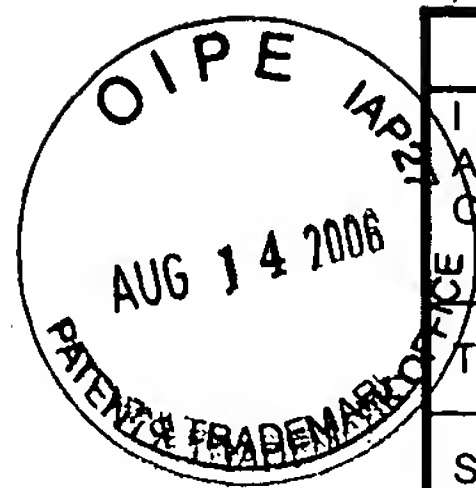
ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Response <input type="checkbox"/> After Final <input type="checkbox"/> Version With Markings Showing Changes <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input checked="" type="checkbox"/> Information Disclosure Statement w/11 References <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application  <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53  <input type="checkbox"/> Copy of Notice	<input type="checkbox"/> Copy of an Assignment <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and Accompanying Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, by Assignee to Exclusion of Inventor Under 37 C.F.R. §3.71 With Revocation of Prior Powers <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Small Entity Statement <input type="checkbox"/> Request for Refund	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> ADDITIONAL ENCLOSURE(S) (PLEASE IDENTIFY BELOW): <input checked="" type="checkbox"/> RETURNED STAMPED POSTCARD
Remarks		
AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT 08-1641 FOR ANY FEES DUE IN CONNECTION WITH THIS PAPER, REFERENCING ATTORNEY'S DOCKET NO. 43369-0001		


SIGNATURE OF APPLICANT, ATTORNEY OR AGENT			
Firm or Individual name	HELLER EHRMAN LLP 275 Middlefield Road, Menlo Park, California 94025	JAMES A. FOX (Reg. No. 38,455) Telephone: (650) 324-7000	Facsimile: (650) 324-0638
Signature			
Date	August 14, 2006	Customer Number:	25213

CERTIFICATE OF EXPRESS MAILING			
I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated below and addressed to: MAIL STOP xxxxx, Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450, on this date: August 14, 2006.x			
Express Mail Label EV 765 972 675 US			
Typed or printed name	ELENA TORRES		
Signature		Date	August 14, 2006

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop \_\_\_\_, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

5



CERTIFICATE OF EXPRESS MAILING			
I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated below and addressed to: Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA on the date indicated below.			
Express Mail Label: EV 765 972 675 US			
Typed or print name	Elena Torres		
Signature		Date	August 14, 2006

PATENT

Attorney Docket No.: 43369-0001

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**PATENT APPLICATION**

Inventor(s): Kingston Mills et al.

Application No.: 10/575,291

Filed: April 11, 2004

Title: FILAMENTOUS HAEMAGGLUTININ IN THE  
TREATMENT AND/OR PROPHYLAXIS OF  
IMMUNE-MEDIATED DISORDERS

Art Unit: Unassigned

Examiner: Unassigned

**INFORMATION DISCLOSURE STATEMENT**

**UNDER 37 C.F.R. §1.97**

Mail Stop: AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy is provided of each foreign patent, each cited pending unpublished U.S. application, and all additional publications other than U.S. patents and U.S. patent application publications. 37 C.F.R. §§1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

☒ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):

- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage  
-- OR --
- ☒ (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:

- ☐ a certification as specified in §1.97(e) is provided below; or
- ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:

- A. a certification as specified in §1.97(e) is completed below; and
- B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; and
- C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 08-1641 (Docket No.: 43369-0001).

Respectfully submitted,

HELLER EHRMAN LLP

By: 

James A. Fox  
Reg. No.: 38,455

Dated: August 14, 2006

HELLER EHRMAN LLP  
275 Middlefield Road  
Menlo Park, CA 94025-3506  
Telephone: 1.650.324.7115  
Facsimile: 1.650.324.0638  
Customer No.: 25213

**INFORMATION DISCLOSURE  
STATEMENT**
**PTO-1449**
**ATTY. DOCKET NO.**

43369-0001

**SERIAL NO.**

10/575,291

**APPLICANT:** Kingston Mills et al.

**FILING DATE:** 4/11/2004

**GROUP:** Unassigned

**U.S. PATENT DOCUMENTS**

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	4,784,589	11/15/1988	Robinson et al.	424	9	
	4,997,915	05/05/1991	Tan et al.	530	396	
	5,681,571	10/28/1997	Holmgren et al.	424	236	
	5,725,860	03/10/1998	Elliott	424	240.1	
	5,728,385	03/17/1998	Classen	424	201.1	
	6,051,240	04/18/2000	Suehara et al.	424	240.1	
	6,153,203	11/28/2000	Holmgren et al.	424	236.1	
	6,288,214	11/11/2001	Hook et al.	530	387.1	
	6,322,796	11/27/2001	Holmgren et al.	424	236.1	
	6,403,080	06/11/2002	Segal	424	93.1	
	6,632,436	10/14/2003	Segal	424	192.1	
	6,365,163	04/02/2002	Holmgren et al.	424	236.1	
	6,638,739	10/28/2003	Classen	435	69.3	
	6,660,261	12/09/2003	Mielcarek et al.	424	93.4	
	6,689,757	02/10/2004	Craig	514	44	
	US 2004/0047867	03/11/2004	Capron et al.	424	184.1	

**FOREIGN PATENT DOCUMENTS**

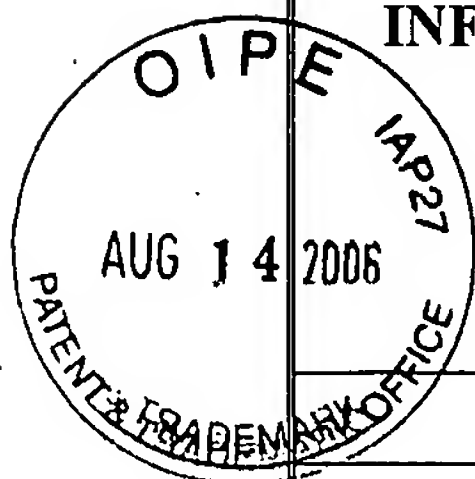
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	01/93906	13/12/2001	WO	A61K	39/39	<input type="checkbox"/>	<input type="checkbox"/>
	95/28486	26/10/1995	WO	C12N	15/31		
	96/31535	10/10/1996	WO	C07K	14/235		
	2 768 928	06/10/1998	FR				
	0 267 998	25/05/1988	EP				

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	Keogh et al., "Induction of Antigen-Specific Regulatory T Cells by Coadministration of Peptides and Pathogen-Derived Molecules that Stimulate Dendritic Cell IL-10 Production", Immunology 107: Suppl 1, Abstract 1.14 (December 2002).
	McGuirk et al., "Pathogen-Specific Regulatory T Cells Provoke a Shift in the Th1/Th2 Paradigm in Immunity to Infectious Diseases", Trends in Immunology, vol. 23, no. 9, September 2002. pp. 450-455.

**EXAMINER**
**DATE CONSIDERED**

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



<b>INFORMATION DISCLOSURE STATEMENT</b>  <b>PTO-1449</b>			ATTY. DOCKET NO. 43369-0001		SERIAL NO. 10/575,291	
			APPLICANT: Kingston Mills et al			
			FILING DATE: 4/11/2004		GROUP: Unassigned	
<b>U.S. PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
						YES
						<input type="checkbox"/> <input type="checkbox"/>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>						
	McGuirk et al., "Pathogen-Specific T Regulatory 1 Cells Induced in the Respiratory Tract by a Bacterial Molecule that Stimulates Interleukin 10 Production by Dendritic Cells: A Novel Strategy for Evasion of Protective T Helper Type 1 Responses by <i>Bordetella Pertussis</i> ", J. Exp. Med-The Rockefeller University Press, 0022-1007/2002/01/221/11, vol. 195, no. 2, January 21, 2002, pp. 221-231.					
	McGuirk et al., "Filamentous Hemagglutinin and Pertussis Toxin from <i>Bordetella Pertussis</i> Modulate Immune Responses to Unrelated Antigens", The Journal of Infectious Diseases, 2000;182: pp/1286-1288.					
	McGuirk et al., "Direct Anti-Inflammatory Effect of a Bacterial Virulence Factor: IL-10 Dependent Suppression of IL-12 Production by Filamentous Hemagglutinin from <i>Bordetella Pertussis</i> ", Eur. J. Immunol., 2000.30:, pp.415-422.					
	Poulain-Godefroy et al., "Adjuvant Activity of Free Bordetella Pertussis Filamentous Haemagglutinin Delivered by Mucosal Routes", Scandinavian Journal of Immunology 58, pp. 503-510.					
EXAMINER			DATE CONSIDERED			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.